

Amendments to the Claims

This listing of claims will replace all prior versions, and listings, of claims in the application:

1. (previously presented) A method for evaluating a clinical trial protocol specification, comprising the steps of:

encoding into a database, workflow tasks called for in a clinical trial protocol specification not yet in execution, including substeps of writing, into protocol specification objects of said database, specifications of protocol events that said protocol specifies to occur during execution of said protocol, and relationships that said protocol specifies among said protocol events;

during said step of encoding workflow tasks but not during any of said substeps, identifying an operational uncertainty in which said protocol specification contains at least one of the following deficiencies: said protocol specification fails to specify a particular parameter for use during protocol execution, or said protocol specification specifies such a parameter with less precision than is required by a slot in said database for encoding the parameter, or said protocol specification contains at least two such parameter specifications which are in conflict;

encoding into said database in association with at least a particular one of said protocol specification objects in said database, before execution of said clinical trial protocol, an indication that said operational uncertainty exists with respect to said particular object; and

in dependence upon protocol specification objects in said database, before execution of said clinical trial protocol, displaying a graphical-visual representation of said protocol, said graphical-visual representation including a human-perceptible indication that said particular protocol specification object has said operational uncertainty associated therewith.

2. (original) A method according to claim 1, wherein said database is an object-oriented database.

3. (previously presented) A method according to claim 1, wherein said protocol specification objects include protocol event objects describing protocol events, and temporal constraint objects describing temporal constraints among said protocol event objects.

4. (previously presented) A method according to claim 3, wherein said step of displaying comprises the step of displaying each of said protocol specification objects in a color which differs depending on whether an operational uncertainty is associated therewith.

5. (previously presented) A method according to claim 1, wherein said step of displaying comprises the step of displaying each of said protocol specification objects in a color which differs depending on whether an operational uncertainty is associated therewith.

6. (previously presented) A method according to claim 1, wherein said operational uncertainty comprises said protocol specification containing at least two parameter specifications which are in conflict.

7. (previously presented) A method according to claim 1, wherein said operational uncertainty comprises said protocol specification specifying a parameter with less precision than is required by a slot in said database.

8. (previously presented) A method according to claim 1, wherein said operational uncertainty comprises an omitted parameter in said protocol specification.

9. (original) A method according to claim 1, wherein said operational uncertainty concerns a temporal constraint among at least two of said protocol events.

10. (previously presented) A set of at least one computer readable medium, said set carrying a machine readable database which includes protocol specification objects describing protocol events that a protocol specification specifies to occur during execution of said protocol, and relationships among said protocol events,

said database further including a disambiguation comment object which identifies an operational uncertainty in which said protocol specification contains at least one of the following deficiencies: said protocol specification fails to specify a particular parameter for use during protocol execution, or said protocol specification specifies such a parameter with less precision than is required by a slot in said database for encoding the parameter, or said protocol

specification contains at least two such parameter specifications which are in conflict, said disambiguation comment object being associated with at least a particular one of said objects in said database.

11. (original) A medium according to claim 10, wherein said database is an object-oriented database.

12. (previously presented) A medium according to claim 10, wherein said protocol specification objects include protocol event objects describing protocol events, and temporal constraint objects describing temporal constraints among said protocol event objects.

13. (original) A medium according to claim 12, wherein said disambiguation comment object is associated with one of said protocol event objects.

14. (original) A medium according to claim 12, wherein said disambiguation comment object is associated with a particular one of said temporal constraint objects.

15. (original) A medium according to claim 14, wherein said operational uncertainty concerns the amount of time allowed to elapse between two protocol events identified by said particular temporal constraint object.

16. (previously presented) A medium according to claim 12, wherein said protocol specification objects further include workflow task objects.

17. (original) A medium according to claim 16, wherein each of said workflow task objects is associated with at least one of said protocol event objects.

18. (original) A medium according to claim 16, wherein said disambiguation comment object is associated with one of said workflow task objects.

19. (previously presented) A medium according to claim 10, wherein said operational uncertainty comprises said protocol specification containing at least two parameter specifications which are in conflict.

20. (previously presented) A medium according to claim 10, wherein said operational uncertainty comprises said protocol specification specifying a parameter with less precision than is required by a slot in said database.

21. (previously presented) A medium according to claim 10, wherein said operational uncertainty comprises an omitted parameter in said protocol specification.

22. (original) A medium according to claim 10, wherein said operational uncertainty concerns the amount of time allowed to elapse between two of said protocol events.

23-41. (canceled)

42. (previously presented) A method for evaluating a clinical trial protocol specification, comprising the steps of:

encoding into a database, workflow tasks called for in a clinical trial protocol specification not yet in execution, including substeps of writing, into protocol specification objects of said database, specifications of protocol events that the protocol specifies to occur during execution of the protocol, and relationships that the protocol specifies among said protocol events;

during said step of encoding workflow tasks but not during any of said substeps, identifying an operational uncertainty in which said protocol specification contains at least one of the following deficiencies: said protocol specification fails to specify a parameter for use during protocol execution, or said protocol specification specifies such a parameter with less precision than is required by a slot in said database for encoding the parameter, or said protocol specification contains at least two such parameter specifications which are in conflict;

encoding into said database in association with at least a particular one of said protocol specification objects in said database, before execution of said clinical trial protocol, an

indication that said operational uncertainty exists with respect to the particular protocol specification object; and

in dependence upon objects in said database, before execution of said clinical trial protocol, outputting a report setting forth the operational uncertainties identified in said protocol and encoded into said database.

43. (previously presented) A method according to claim 42, further comprising the steps of:

encoding into a protocol disambiguation object said indication that said operational uncertainty exists; and

associating said protocol disambiguation object with said particular protocol specification objects in said database.

44. (previously presented) A method according to claim 43, wherein said protocol specification objects include protocol event objects describing protocol events, and temporal constraint objects describing temporal constraints among protocol events described in said protocol event objects,

and wherein said step of associating comprises the step of associating said protocol disambiguation object with one of said protocol event objects or one of said temporal constraint objects in said database.

45. (original) A method according to claim 42, wherein said database is an object-oriented database.

46. (original) A method according to claim 42, further comprising the step, prior to said step of outputting, of sorting a list of said operational uncertainties identified in said protocol and encoded into said database.

47. (original) A method according to claim 42, wherein said step of outputting comprises the step of outputting in tabular form the operational uncertainties identified in said protocol and encoded into said database.

48. (previously presented) A method according to claim 42, wherein said operational uncertainty comprises said protocol specification containing at least two parameter specifications which are in conflict.

49. (previously presented) A method according to claim 42, wherein said operational uncertainty comprises said protocol specification specifying a parameter with less precision than is required by a slot in said database.

50. (previously presented) A method according to claim 42, wherein said operational uncertainty comprises an omitted parameter in said protocol specification.

51. (previously presented) A method according to claim 42, wherein said operational uncertainty concerns a temporal constraint among at least two of said protocol events specification.

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